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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,694	01/17/2006	Irina A Buhimschi	035394-0295	6784

22428 7590 04/17/2007
FOLEY AND LARDNER LLP
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER

VENCI, DAVID J

ART UNIT	PAPER NUMBER
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1641

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	04/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,694	BUHIMSCHI ET AL.	
	Examiner	Art Unit	
	David J. Venci	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on January 10, 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 61-65,67,68,77,82,90 and 91 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 61-65,67,68,77,82,90 and 91 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

This application contains the following inventions which are not linked so as to form a single general inventive concept under PCT Rule 13.1. Restriction is required under 35 U.S.C. 121 and 372. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 61-65, 67 and 68, drawn to a kit
- II. Claims 77 and 91, drawn to methods comprising, *inter alia*, a diagnostic correlation step
- III. Claims 82 and 90, drawn to an algorithm

According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The product of Invention I is used in the methods of Inventions II and III. However, the technical feature linking Inventions I, II and III does not constitute a special technical feature as defined by PCT Rule 13.2 because the technical feature does not define a contribution over the prior art.

Cole *et al.*, 504 FEBS LETTERS 5 (2001), also teach absorbents (see e.g., p. 5, right column, 2. MATERIALS AND METHODS, 2.1 *Isolation and purification of antimicrobial peptides from human nasal secretions*, "nasal secretions", "vacuum", "catheter tip", "strong cation-exchange HPLC", "Vydac 218TP C18", "MALDI-TOF") for HNP-1, HNP-2 (see e.g., p. 5, right column, line 1 and note 9), calgranulin A and calgranulin C (see e.g., p. 5, right column, first full paragraph), and instructions (see e.g., p. 5, top right corner, "FEBS Letters 504 (2001) 5-10", bottom left corner, "Corresponding author").

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Therefore, unity of invention is lacking because the technical feature linking Inventions I, II and III does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.¹

Applicant is advised that a complete reply to this requirement must include: (i) an election of an invention to be examined even if the requirement is traversed² (37 CFR 1.143), and (ii) identification of the claims encompassing the elected invention. An argument that claims are allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



David J Venci
Examiner
Art Unit 1641

djv

LONG V. LE 04/03/07
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

¹ Examiner requires restriction between product and process claims. Where Applicant elects to prosecute claims directed to a product, and the product claims are subsequently found allowable, Examiner will consider withdrawing the instant restriction requirement and rejoining non-elected, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claims (i.e., all the process claims must include all the limitations of the allowable product claims). Examiner will not rejoin non-elected, withdrawn process claims that are not commensurate in scope with the allowable product claims. See MPEP § 821.04(b). Thus, where Applicant elects to prosecute claims directed to a product, Examiner advises Applicant to continually amend the non-elected, withdrawn process claims during prosecution to require all the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Upon rejoinder, Examiner will fully examine the rejoined process claims in accordance with 37 CFR 1.104 for compliance with all criteria for patentability, including the requirements of 35 U.S.C. 101, 102, 103 and 112. Examiner further advises Applicant that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where Examiner withdraws the restriction requirement before the patent issues. See MPEP § 804.01.

² Applicant may elect an invention or species with traverse or without traverse. To reserve a right to petition, Applicant must elect with traverse. Should Applicant traverse on the ground that the inventions or species are not patentably distinct, Applicant should clearly admit on the record, or submit or identify evidence on the record that the inventions or species are obvious variants. If Examiner finds one Invention unpatentable over the prior art, Examiner may use the evidence or admission of record to reject other inventions under 35 U.S.C.103(a).